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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/982,554	10/18/2001	Mathias C. Zohoungbogbo	601-17c1	8007

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EXAMINER

HUI, SAN MING R

ART UNIT PAPER NUMBER

1617

DATE MAILED: 04/15/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/982,554	ZOHOUNGBOGBO, MATHIAS C.	
	Examiner	Art Unit	
	San-ming Hui	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 10 December 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 27-39 and 41-44 is/are pending in the application.
- 4a) Of the above claim(s) 27-39 and 41-43 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 44 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on December 10, 2003 has been entered.

The cancellation of claim 40 and the addition of claims 41-44 in amendments filed December 10, 2003 are acknowledged.

Newly submitted claims 41-43 and amended claims 27-39 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: the claims are drawn to a dietary weight loss method whereas the claims before amendments were drawn to a method of treating the side effects of ketogenic diet. The two method are having two different functions and therefore, they are distinct and unrelated from each other.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 27-29 and 41-43 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

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Claim 44 will be examined to the extent they read on the elected invention.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 44 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

In the instant case, the specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims. The instant specification fails to provide information that would allow the skilled artisan to practice the instant invention without undue experimentation. Attention is directed to *In re Wands*, 8 USPQ2d 1400 (CAFC 1988) at 1404 where the court set forth the eight factors to consider when assessing if a disclosure would have required undue experimentation. Citing *Ex parte Forman*, 230 USPQ 546 (BdApls 1986) at 547 the court recited eight factors:

- 1) the quantity of experimentation necessary,
- 2) the amount of direction or guidance provided,
- 3) the presence of absence of working examples,
- 4) the nature of the invention,

- 5) the state of the prior art,
- 6) the relative skill of those in the art
- 7) the predictability of the art, and
- 8) the breadth of the claims.

Applicant fails to set forth the criteria that define the useful synergistic combination of " benfluorex, ursodesoxycolic acid, metformin, and pancreatine IX F.U." as herein claimed. Additionally, Applicant fails to provide information allowing the skilled artisan to ascertain these compounds without undue experimentation. In the instant case, no example is set forth the synergistic combination of " benfluorex, ursodesoxycolic acid, metformin, and pancreatine IX F.U.", thereby failing to provide sufficient working examples. It is note that synergistic effect is unpredictable, requiring each embodiment to be individually assessed for physiological activity. Examiner notes that synergistic effect has to be demonstrated; and in the instant case, no data was demonstrated such effect. The instant claims read on any amount of " benfluorex, ursodesoxycolic acid, metformin, and pancreatine IX F.U.", necessitating an exhaustive search for the embodiments suitable to practice the claimed invention. Applicants fail to provide information sufficient to practice the claimed invention, absent undue experimentation.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

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Claims 44 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The recitation “produces a synergistic effect of reducing concentration of a plurality of internal body chemicals.” in claim 44, lines 3-4 renders the claims indefinite as to method steps required to achieve the recited results.

The recitation of “a plurality of internal body chemicals” in claim 44 renders the claims indefinite as to what internal body chemicals encompassed thereby.

Claim 44 is drawn to a method of treating persons who is subject to ketogenic diet that suffers from the side effect of ketogenic diet employing agents such as benfluorex, ursodesoxycolic acid, metformin, and pancreatine IX F.U.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.

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2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claim 44 is rejected under 35 U.S.C. 103(a) as being unpatentable over Marquie et al. (Life Sciences, 1998; 63(1):65-76), Pentikainen et al. (Annals of Medicine, 1990 ;22 :307-312), and Poupon et al. (Hepatology, 1993; 17(4): 577-582) in view of Spasmo-canulase® Bitab® package insert (July 1989), references of record.

Marquie et al. teaches benfluorex as useful in treating hypercholesterolemia (See abstract, also page 74, whole page).

Pentikainen et al. teaches the cholesterol lowering effect of metformin (See the abstract, also page 309, Table 2).

Poupon et al. teaches ursodesoxycholic acid as useful in lowering hypercholesterolemia (See particularly the abstract).

The references do not expressly teach the method of treating the side effects of a ketogenic diet with the combination of benfluorex, metformin and ursodesoxycholic acid. The references do not expressly teach the herein claimed amount ratio employed. The references do not expressly teach the employment of pancreatin and sodium dehydrocholate with benfluorex and metformin.

Spasmo-canulase® Bitab® package insert teaches Spasmo-canulase® Bitab®, which contains pancreatin and sodium dehydrocholate, is useful in treating abdominal cramps associated with flatulence.

One of ordinary skill in the art would have been motivated to treat side effects of a ketogenic diet (hypercholesterolemia being one of the side effects of ketogenic diet)

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with the combination of benfluorex, metformin and ursodesoxycholic acid. Combining and employing two or more agents which are known to be useful to lowering hypercholesterolemia individually into a single method useful for the very same purpose (treating hypercholesterolemia) is prima facie obvious. See *In re Kerkhoven* 205 USPQ 1069. One of ordinary skill in the art would have been motivated to incorporate pancreatin and sodium dehydrocholate in the treatment method herein because Spasmo-canulase[®] Bitab[®], which contains pancreatin and sodium dehydrocholate, is known for relieving abdominal cramps associated with flatulence. Since flatulence and abdominal cramps are the common side effects of metformin, employing Spasmo-canulase[®] Bitab[®] would be reasonably expected to be effective in relieving the side effects of metformin and be useful in the herein claimed method, which utilize metformin. Furthermore, the optimization of result effect parameters (i.e., dosage range, dosing regimens) is obvious as being within the skill of the artisan.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to San-ming Hui whose telephone number is (703) 305-1002. The examiner can normally be reached on Mon 9:00 to 1:00, Tu - Fri from 9:00 to 6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan, PhD., can be reached on (571) 272-0629. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

A handwritten signature in black ink, appearing to read 'San-ming Hui', is positioned above the printed name.

San-ming Hui
Patent Examiner
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